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**Unanticipated, irregular bleeding associated with the
implant and therapeutic interventions**

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Unanticipated, irregular bleeding associated with the implant and therapeutic interventions

ABSTRACT

Objectives

To review irregular bleeding as reason for ‘premature’ contraceptive implant removal and identify recommendations with regard to bleeding management, which may help to improve implant retention.

Methods

A qualitative study was undertaken in which twenty young women who had their implants removed ‘prematurely’ and nine contraceptive practitioners were interviewed about their experiences of the contraceptive implant.

Results

The most common reason for premature implant removal was intolerance of bleeding patterns despite what was generally felt to be adequate counselling on this side effect. Clinicians appeared to lack a comprehensive strategy to help improve bleeding patterns, beyond reassurance and encouragement to persevere.

Conclusions

It is important to appreciate the true impact of erratic bleeding on young women. A pragmatic, therapeutic approach to manage bleeding problems should be employed as soon as bleeding becomes difficult to tolerate. This includes management with the Combined Oral Contraceptive pill and mefenamic acid.

Key message points

- Young women warned of the possibility of unanticipated bleeding as an implant side effect may still be unprepared for the impact this has.
- Encouragement to tolerate side-effects can push women towards a ‘tipping point’ when immediate implant removal is requested and there is disengagement with services.
- Bleeding related issues can be managed in clinical practice, thus helping young women to retain this method of contraception, if they wish to do so.

Introduction

The contraceptive implant (Implanon [™], Nexplanon[™]) is widely recognised as a reliable and cost-effective form of contraception [1], [2]. Continuation rates, however, are of concern. In small scale studies in the UK, Smith and Reuter [3] report continuation rates (within one year) for the implant of

between 67% and 78%; whilst Lakha and Glasier [4] report 75%. Blumenthal et al [5] reports an overall discontinuation rate of 32.7% (within five years) based on an analysis of 11 international clinical trials. It has been calculated that 60% to 64% of implant removals are for irregular/unpredictable bleeding [4], [6], [7].

This paper draws on the findings of a recent research project, commissioned by the London Sexual Health Programme (on young women and implant removal), in order to make suggestions for the management of unanticipated, irregular bleeding associated with the contraceptive implant. The research project sought to identify the reasons why some young women have their contraceptive implant removed within one year of insertion and made several recommendations as to how retention of the implant could be maximised [8]. This article draws on this study in order to make suggestions for bleeding management.

Methods

The project was a qualitative study in which twenty young women (aged 16-22) were interviewed. Most had had their implants removed within a year of insertion, and all of them within three years. Their contraceptive choices were examined, using semi-structured qualitative interviews. The women were identified with the help of practitioners at the sexual health clinics in four London health authorities. Participants were purposively selected to meet the age and 'early' implant removal criteria. Nine Contraceptive and Sexual Health Service clinicians were interviewed also using a semi-structured format. The clinicians taking part in the study may or may not have counselled the young women we interviewed in the study. No attempt was made to match the two sets of participants. The data was analysed using thematic analysis [9] by means of NVivo Software.

Results

Unsurprisingly, the most common reason given for 'premature' removal was intolerance of bleeding patterns. In some cases, this was the length and irregularity of bleeding and in other cases it was the lack of a regular menstrual period that caused concern. In line with previous research[10], the interviewed clinicians also identified bleeding irregularity as the most common problem but there was inconsistency within the clinician group about how this could be managed.

The contraceptive consultation

Guidelines for standard practice in implant provision emphasises the importance of adequate counselling about side effects, especially bleeding irregularities, before implant insertion [11]. In the research project, almost universally, the clinicians interviewed believed they provided adequate counselling before insertion. They also noted that irregular bleeding patterns were felt to be the main side effect of the implant and this was therefore the issue most extensively discussed in counselling prior to fitting. They felt it was very important that the bleeding pattern of the implant was communicated and understood by the young woman at the time of the consultation.

An underlying belief in the efficacy of extensive counselling led some clinicians to blame inadequate counselling for requests for what was viewed as 'premature' removal.

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To put it in and take it out and what we find is when their people have had poor counselling, they come in and they want it out straight away so you may have a person whose had an implant in for about six weeks and she had it put in on her period, her period has continued and so coming up to the six weeks she getting anxious, she's getting worried: 'why is this taking so long?'. (District 3, Interview 2)

Most clinicians mentioned that they gave the patient a 'leaflet' at the time of counselling (Usually the FPA Contraceptive implant leaflet [12]). The results from our study, however, indicate that the messages from this leaflet are not being absorbed; and also that women who may have trouble reading the leaflet may not mention this at the initial consultation.

Our analysis of the full data set revealed four issues of note derived from contraceptive counselling.

1. There were significant variations in the standard of pre-insertion counselling.
2. There was a mismatch between the young women's recollection of their contraceptive counselling and the counselling described by the clinicians interviewed. This indicates a discrepancy between what the clinicians thought they were communicating, and what the young women themselves took away from the exchange. Although the clinicians taking part in the study may not have been the same ones who had counselled the young women in the study, this difference is worth noting. It is possible that clinicians are over-confident about the efficacy of their counselling on the possibility of bleeding irregularities.
3. Even if the young women did recall having been counselled about the possibility of problematic bleeding, they were unprepared for the consequences of this on their personal lives.
4. They hoped that the bleeding would not happen to them.

'She gave me a leaflet, I'm dyslexic so I need someone to talk to me in person and be honest with me'.(Jo,20)

They didn't say anything about bleeding. I didn't get told nothing about that. (Stacy, 19)

I thought it won't happen to me. I thought it would be only for a little bit, I didn't think it would be for four months, you know it's quite a while for bleeding. I just underestimated what she was saying basically, because I will admit she did tell me, she did but I just thought it won't happen to me. (Aysa, 17)

The reality of bleeding for young women

The young women had understood the bleeding they experienced whilst using the implant in terms of their 'period', and had not anticipated their bleeding patterns becoming worse. Although many had tolerated bleeding patterns that they found distressing for varying periods of time, those seeking 'premature' removal had eventually found the unpredictability and length of bleeding

patterns unbearable. Bleeding was experienced as exhausting, bad for sexual relationships and expensive in terms of the need to buy sanitary protection. Of particular concern was the constant worry about the potential embarrassment of not knowing when they may start bleeding.

Women who did not experience any bleeding could also be unhappy. The perception that regular menstrual bleeding represents normality can be important and women can be anxious about their fertility when they are not experiencing a regular period. Additionally some of the young women interviewed believed that the bleeding was the cause of other problems such as fatigue, anaemia and weight gain.

I have to obviously decide what clothes to wear and you have to be very cautious because I can't be on the bus with a wet patch, that's embarrassing. (Grace, 19)

I can't handle the periods, it was constant, constant just.... And you'd have a two day break and then it would come back on for two months and then you'd have a like a week break and then it would come back on for a month and it was just a joke. (Janey, 18)

I don't think it's very healthy not to have a period...I don't want the situation...when I'm older they say it's going to be hard for me to have kids because I had the implant. (Aysa, 17)

I just constantly bled for three months straight.... I was constantly tired, the doctors diagnosed anaemia so I got to the point that it was time to take it out. (Ella, 22)

The period makes you eat more and I'm trying to lose weight at the moment. (Stacy, 19)

Many of the clinicians interviewed for this study also expressed frustration with the unpredictable nature of implant bleeding:

We would counsel to say wait four to six months but the truth is there is actually no proper definition of how long the unpredictable bleeding pattern is going to continue, we just don't know. We just don't know. (District 2, Interview 2)

The big let-down, which is a real let-down, is the problem with the bleeding because we can't..... because it's so unpredictable and so varied and there is no way....I can't predict who is going to get what (District2, Interview2)

However, most clinicians also expressed a sense of disappointment when asked to remove an implant 'prematurely' and specified time periods, for example six months to a year, when they would attempt to persuade the patient to retain the implant. However, as we have shown elsewhere [8] this sort of approach could contribute towards young women reaching a 'tipping point' – this is the point at which nothing short of removal is acceptable. Resistance to removal can also lead to loss of respect for the clinician and the feeling that bodily autonomy has been overridden.

Reaching the 'tipping point'

The study found that the request for ‘premature’ implant removal was usually multi-factorial. Often several factors contributed – not only an accumulation of side effects but also external factors such as change in relationship and a sense of lost autonomy. Although another factor may have proved to be the final impetus for removal, it was clear from the data that bleeding irregularity, was either the major, or the only, underlying cause of dissatisfaction pushing young women towards their individual ‘tipping point’. When this happened there was nothing further that could be done to help alleviate the symptoms because they were despondent having been encouraged to tolerate side-effects too long, rather than to return to the clinic as soon as they were concerned.

There was some evidence that interventions were attempted, but that these may have been too late. Some young women had experienced an attempt at controlling bleeding and this may not have worked for them, or they had not been able to comprehend the rationale of taking something additional when the obvious cause could be removed.

I thought that would be too much taking the pill as well...the pill makes you put on weight as well and I just didn't feel good about taking it. (Stacy,1 9)

Additionally, although several of the clinicians interviewed acknowledged that there were methods of managing bleeding, they did not appear to be aware of a rationale as to what therapeutic intervention could be used and when. As mentioned above, there also appeared to be frustration amongst the clinicians about the unpredictability of the bleeding, rather than any confidence about the possibility of pro-actively helping with this side-effect.

The majority of the reasons why people want it removed is because of irregular bleeding and they may have bled now for six weeks, they're really fed up so then trying to convince somebody, 'keep it in and I'll give you something on top of it and it'll settle'... sometimes it's very difficult to maybe convince them to go down that route. (District1, Interview 3)

One of the clinicians acknowledged that a key to helping women continue with the method could be to advise them - at the time of pre-insertion counselling - about how any future bleeding problems could be managed.

Whereas...you give them good guidance, tell them they can have something to control the bleeding and sometimes that can actually almost stop the bleeding, not always but it can do and sort of revert the system back to, to sort of being a non-period type method, that they will, they will be happy to continue it.(District3, Interview 2)

Discussion

It is important to remember that the young women’s recollections of their counselling may differ from the recollections of clinicians. Our interviews with practitioners indicate that these clinicians believe they are counselling adequately, and are likely to assume that requests for ‘premature’

removal are due to inadequate counselling. This may be the case for some women, but our study has shown that even in cases where young women have been made aware of the possibility of irregular bleeding, the clinician's messages are not always being fully absorbed. The young women each have their own interpretations of the advice they have been given, and individualised responses to their experiences of side effects. It was apparent from our study that the predominant reason for request for implant removal was irregular bleeding. It was also evident that:

1. Young women had not been prepared for the reality of prolonged bleeding or irregular bleeding patterns even when they could recall being informed at their initial consultation.
2. They often persevered, waiting for the bleeding pattern 'to settle', so often tolerated significant amount of discomfort and inconvenience.
3. Some described bleeding in conjunction with other side effects as being problematic.

It was also apparent that the clinicians were often frustrated and did not have a systematic approach to what could be done to help to improve the situation. Patients were frequently just advised to 'persevere' with the symptoms in the hope that these may ultimately resolve – however, when the situation did not resolve, the 'therapeutic window' for some form of intervention had been missed and the women had reached a 'tipping point' at which intervention was no longer possible. Also, it is important to recognise the real impact of troublesome bleeding – the impact it has on sex-life, relationships and finances, and the anxiety caused by unpredictability. It would therefore seem important to intervene as soon as possible when bleeding is presented as a problem, rather than encouraging acceptance of the situation.

Research into methods of controlling the problematic bleeding related to the contraceptive implant is inconclusive, so a pragmatic approach to the management of bleeding problems should be employed [13].

During the normal menstrual cycle, estrogen is responsible for the early development of endometrial glands and spiral arterioles and for proliferation of the uterine stroma. Progestogen is responsible for the dilatation and thinning of the spiral arterioles. Continuous low dose progestogen (released by the implant) predisposes to breakthrough bleeding because the vessels proliferate and become disordered with a 'leaky' basement membrane, there is decreased glandular and stromal support, and reduced epithelial integrity [14]. High dose progestogen leads to pseudo-decidualisation and endometrial stability.

Prostaglandins are also important in the mechanism which controls uterine bleeding. Inflammatory prostaglandins, produced by conversion of arachidonic acid by cyclo-oxygenase 2, recruit white cells and sensitise pain receptors. White cell influx is also important in breakthrough bleeding, so reducing this process by provision of non-steroidal anti-inflammatory agents e.g. mefenamic acid, has a potential effective role.

Guidance for the control of unscheduled bleeding related to hormonal contraception [15] recommends that other possible causes for bleeding are initially excluded, e.g. exclusion of sexually transmitted infection, pregnancy and other genital tract pathology. Once the clinician is confident that the cause of the bleeding is implant-related a number of options are available.

1. The best approach is to provide estrogen, usually in the form of the combined oral contraceptive pill. This can be given either cyclically or continuously, initially for three months. If symptoms resolve, but then deteriorate when treatment is stopped, it can be given for the entire duration of implant use if necessary. A preparation such as Microgynon™ is ideal, as this is a relatively progestogenic preparation. The estrogen will lead to stromal proliferation which helps to support the bleeding vessels and the relative high dose of progestogen will promote pseudo-decidual change. There is no reason that this regime cannot be commenced as soon as abnormal bleeding becomes problematic. There is evidence to support the use of estrogen in the management of bleeding with other progestogenic methods [16], and it is this evidence which was extrapolated to provide the FSRH Guidance.
2. In cases where estrogen use is contraindicated e.g. focal migraine, there has sometimes been a tendency to use a desogestrel progestogen only pill (e.g. Cerazette™) to try to alleviate bleeding. However, particularly in the early stages of implant use, this can confound the problem further by contributing to the 'low dose progestogen' instability. In this situation, a better intervention would be to use a non-steroidal anti-inflammatory drug such as mefenamic acid. There is no indication to use an anti-fibrinolytic agent e.g. tranexamic acid, as the mechanism of these drugs is to impair plasmin activation. This action is not important in the management of troublesome implant bleeding, unless there is associated menorrhagia. Cerazette™ may have a role in helping bleeding where implant bleeding has been stable but subsequently becomes troublesome e.g. after one or two years of use.
3. There has been research to study the effect of the antibiotic doxycycline on the troublesome bleeding caused by the implant. It had been proposed that as a powerful matrix metalloproteinase inhibitor (an enzyme responsible for endometrial breakdown and remodelling) it may be beneficial. However, one randomised controlled trial [17] concluded that the benefits of use are not significant. Nevertheless, this does not mean that it may not have a beneficial effect if there is co-existent infection with Chlamydia or Mycoplasma genitalium, which may be contributing to endometrial instability.
4. Finally, there is a role for high dose progestogens when short term arrest of bleeding is required e.g. norethisterone 5mg tds.

Conclusions

In order to maximise compliance with the contraceptive implant, clinicians need to demonstrate an empathetic and pro-active approach to the management of bleeding problems. From the time that contraceptive counselling is first undertaken; bleeding patterns should be discussed with patients, including advice about an 'open door approach' to the management of bleeding problems. It needs to be acknowledged that as soon as the bleeding pattern is distressing to the patient, it is a problem. There are no guarantees that perseverance with the implant without intervention will ensure improvement or acceptance. In fact, if this advice is given and there is no resolution, the patient may lose faith in their medical professional.

If there is no contraindication, the combined oral contraceptive pill is the most effective intervention. If there are contraindications, mefenamic acid e.g. 500mg tds for 1 week can be given. Other management options can be tried on a pragmatic but non-evidence based approach.

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